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Re-evaluation Decision RVD2012-04

Poly[oxyethylene (dimethyliminio)ethylene (dimethyliminio)ethylene dichloride] (POD)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Re-evaluation Decision

After a re-evaluation of the antimicrobial active ingredient poly[oxyethylene(dimethyliminio) ethylene(dimethyliminio)ethylene dichloride], hereafter referred to as POD, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing POD for sale and use in Canada.

An evaluation of available scientific information found that products containing POD do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of POD uses, new risk-reduction measures must be included on the labels of all products. Additional confirmatory data are being requested as a result of this re-evaluation

The regulatory approach for the re-evaluation of POD was first presented in Proposed Re-evaluation Decision PRVD2011-13, *Poly[oxyethylene(dimethyliminio) ethylene(dimethyliminio)ethylene dichloride] (POD)*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process for the re-evaluation of POD as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2011-13. To comply with this decision, registrants of products containing POD will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

POD has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency Reregistration Eligibility Decision documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of POD. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The United States Environmental Protection Agency re-evaluated POD and published its conclusions in a 2007 Reregistration Eligibility Decision.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2011-13, *Poly[oxyethylene(dimethyliminio) ethylene(dimethyliminio)ethylene dichloride] (POD)*.

What Is POD?

POD is an antimicrobial active ingredient used for control of algae in swimming pools, spas, hot tubs and decorative fountains. It is also registered for control of algae, bacteria and fungi in cooling towers, industrial air washing systems, metal working fluids, and starch solutions used in the production of paper, paperboard, and adhesives. Commercial products containing POD are applied by workers by open pour or liquid pump. Domestic products containing POD can be applied by homeowners by open pour.

Health Considerations

Can Approved Uses of POD Affect Human Health?

POD is unlikely to affect your health when used according to the revised label directions.

People could be exposed to POD through residential and occupational exposure. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

POD is unlikely to affect human health provided that the required risk-reduction measures to further protect workers are implemented.

Environmental Considerations

What Happens When POD Is Introduced Into the Environment?

POD is unlikely to affect non-target organisms due to limited potential for environmental exposure.

Non-target organisms could be exposed to POD in the environment as a result of effluent discharge to waters adjacent to manufacturing facilities. Environmental risk is assessed by the

risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

POD is unlikely to pose an adverse effect to the environment if used according to revised labels. Improvements to environmental label statements and risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of POD, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect workers.
- Additional instructions concerning good hygiene practices in occupational settings.

Environment

- Improvements to advisory label statements and a prohibition of POD use in decorative fountains with fish.

Appendix I lists all required label amendments, including additional instructions related to basic hygiene practices.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix II lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on POD within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing POD

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) For commercial products, the following statements must be included in a section entitled **PRECAUTIONS**.

> KEEP OUT OF REACH OF CHILDREN. Do not mix with any other chemical. Harmful if swallowed. Avoid contact with skin and eyes. Wear a long-sleeved shirt and long pants, chemical-resistant gloves during handling, clean-up and repair activities. In addition, a chemical-resistant apron is required for workers handling end-use products in industrial settings. Wash thoroughly after handling. Immediately remove contaminated clothing and wash before reuse.

II) For domestic products, the following statements must be included in a section entitled **PRECAUTIONS**:

> KEEP OUT OF REACH OF CHILDREN. Do not mix with any other chemical. Harmful if swallowed. Avoid contact with skin and eyes.

III) For commercial products, the following statements must be included in a section entitled **DIRECTIONS FOR USE**.

> **DO NOT** discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans, and other waters.
>
> **DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

IV) For the commercial product with the decorative fountains use (Registration No. 12004), the following statement must be included in the **DIRECTIONS FOR USE** section:

> **DO NOT** use in decorative fountains with fish.

V) For domestic and commercial products, the following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

> Toxic to aquatic organisms.

VI) The label of the commercial end-use product BULAB 6002 LIQUID MICROBICIDE (Registration Number 22092) must be amended to include application rates and application methods.

Appendix II Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrant(s) of the technical active ingredients by the PMRA.

DACO 5.2 Use Description Scenario (material preservative in metal working fluids)

DACO 5.6 Post-application: Passive Dosimetry Data (for workers coming in contact with metal working fluids and/or involved in maintenance/clean-up activities related to use of metal working fluids).